K041169

AUG 2 4 2004

EXHIBIT 2

510(k) Summary

CANAMET CANADIAN NATIONAL MEDICAL TECHNOLOGIES INC.

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Date: July 31, 2004

1. **Identification of the device**
   Proprietary-Trade Name: PIESOMETER MK-1
   Classification Names: DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE,
   Common/Usual Name: Non-invasive automated blood pressure meter.

2. **Equivalent legally marketed devices**
   This product is similar in function and design to the Spacelabs ABP (Ambulatory Blood Pressure), K031479, K941167, K904318, K855127 and, SunTech Accutracker DX, K913844.

3. **Indications for Use (intended use)**
   The device is used to provide data to qualified medical personnel or trained users for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to a 48-hour period. Measurements of systolic, diastolic, and heart rate are made and stored. The device can also be used to provide blood pressure and heart rate data in single measurement mode. The device is also intended to provide preliminary blood pressure data from ambulatory patients for non-time critical applications only. It is for use in hospitals, clinics or physicians offices by a qualified physician or trained staff member under the supervision of that physician. It is also intended for home care use by a trained patient with periodic health consultations from his or her physician. Patient diagnosis is not to be performed solely based on the results of this device.

4. **Description of the Device**
   The Model PIESOMETER MK-1 Digital Blood Pressure Monitor measures systolic and diastolic blood pressure and heart rate using adaptive interference cancellation (signal processing) technologies. The system employs three acoustic sensors (i.e. microphones) in the electronic pressure cuff. During a blood pressure measurement, two acoustic sensors are placed in the traditional location on the patient's biceps. This set of sensors, operating much like a conventional stethoscope, senses the Korotkoff sounds. Unique to the PIESOMETER MK-1 is a second set of a sensor placed in the triceps area. This sensor serves to detect any interference signals that would normally compromise the reading. This allows reading to be taken even in noise and vibration intensive environment. This technology functions by identifying signals lying within the audio frequency and filtering out the interference signal. The CANAMET PIESOMETER is protected by U.S. Patent 6,520,918.

5. Safety and Effectiveness, comparison to predicate device

The results of bench and user/clinical testing indicate that the new device is as safe and effective as the predicate devices.

6. Comparison matrix – new vs. Predicate device

Designation	Spacelabs ABP (Ambulatory Blood Pressure), K031479, K941167, K904318, K855127	SunTech Accutracker DX, K913844.	PIESOMETER MK-1
Operating Principle	Auscultatory Technology Korotkoff sound technique.	Auscultatory Technology Korotkoff sound technique, Motion Tolerant	Auscultatory Technology Korotkoff sound technique, Motion Tolerant
Display	4-digit, 7-segment LCD; systolic, diastolic and heart rate information	32 Character LCD	32 Character LCD
Recording Time	Up to 48 hours	Up to 48 Hours	Up to 48 Hours
Power supply	4 AA alkaline disposable or rechargeable NiCad batteries	Four 1.5 (AA) alkaline batteries	Rechargeable Lithium-Ion battery (Not user replaceable) rechargeable with supplied charger.
External dimensions	1.1"x4.5"x3.4" (2.8 cm x11.4 cm x8.6 cm) Model 90217: 0.97"x3.94"x2.77" (2.5 cm x10.0 cm x7.0 cm)	3.25"W x 5"L x 1.30"D (8.25cm x 12.7cm x 3.3cm)	5.28" x 3.74" x 1.73" (13.4 cm X 9.5cm X 4.4cm)
Memory	Not specified	Over 250 samples of systolic, diastolic, and heart rate.	60 records of systolic, diastolic, and heart rate.
Weight	12.2 oz. (347 g) (with batteries)Model 90217: 9 oz. (255 g) (with batteries)	12.6oz. (357.2 grams)	850 grams
Accessories	Not specified	Multiple cuff sizes	Multiple cuff sizes

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of Canamet that that the "PIESOMETER MK-1" Automated Blood Pressure Monitor is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2004

Canamet Canadian National Medical Technologies, Inc.
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K041169
Trade Name: Piesometer, Model MK-1
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: August 09, 2004
Received: August 10, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041169

Device Name: PIESOMETER MK-1

The device is used to provide data to qualified medical personnel or trained users for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to a 48-hour period. Measurements of systolic, diastolic, and heart rate are made and stored. The device can also be used to provide blood pressure and heart rate data in single measurement mode. The device is also intended to provide preliminary blood pressure data from ambulatory patients for non-time critical applications only. It is for use in hospitals, clinics or physicians offices by a qualified physician or trained staff member under the supervision of that physician. It is also intended for home care use by a trained patient with periodic health consultations from his or her physician.

Patient diagnosis is not to be performed solely based on the results of this device.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for DOZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041169